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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,480	08/15/2005	Volker A. Erdmann	ERD/US/0402	2750
27774	7590	09/24/2007		
MAYER & WILLIAMS PC 251 NORTH AVENUE WEST 2ND FLOOR WESTFIELD, NJ 07090			EXAMINER NOAKES, SUZANNE MARIE	
			ART UNIT 1656	PAPER NUMBER
			MAIL DATE 09/24/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/506,480

Applicant(s)

ERDMANN ET AL.

Examiner

Suzanne M. Noakes

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) 2-6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 8-27-2007.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Group I, claim 1, SEQ ID No: 8 in the reply filed on 16 August 2007 is acknowledged. SEQ ID Nos: 1-7 and 9-12 from claim 1, and claims 2-6 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. The requirement is deemed proper and therefore made Final.

### ***Status of the Application***

2. Claims 1-6 are pending and sequences 1-7 and 9-12 of claim 1 as well as claims 2-6 are withdrawn from further consideration as noted above. Claim 1, drawn to SEQ ID No: 8 is subject to examination on the merits.

### ***Information Disclosure Statement***

3. The information disclosure statement (IDS) submitted on 27 August 2007 has been considered by the examiner. See initialed and signed PTO-1449.

### ***Specification***

4. The disclosure is objected to because of the following informalities: The Examiner notes the amendments to the specification filed 06 January 2006. However, it is noted that in paragraph 008, there are three defined amino acid sequences which are greater than four amino acids in length. While Applicants amended the specification to

include a SEQ ID No.; there is actually no number to which any of the three sequences are assigned and thus the specification fails to comply with the Sequence Rules 37 C.F.R. 1.821-825. \* If the noted sequences are in the sequence listing as filed, Applicants must amend the specification to identify the sequences appropriately by SEQ ID NO. If the noted sequences are not in the sequence listing as filed, Applicants must provide (1) a substitute copy of the sequence listing in both computer readable form (CRF) and paper copy, (2) an amendment directing its entry into the specification, (3) a statement that the content of the paper and CRF copies are the same and, where applicable, include no new matter as required by 37 C.F.R. § 1.821 (e) or 1.821(f) or 1.821(g) or 1.821(b) or 1.825(d), and (4) any amendment to the specification to identify the sequences appropriately by SEQ ID NO:.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 101***

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The peptide as claimed, which can "comprise" SEQ ID No: 8, wherein position three can be Glu, Asp or Gly, has an amino acid sequence duplicative of several found in nature (see prior art rejection below), which will inherently possess the biological

Art Unit: 1656

function of being streptavidin-binding peptide. This, therefore does not constitute patentable subject matter absent recitation of "isolated and purified" in the preamble. See *American Wood v. Fiber Disintegrating Co.*, 90 U. S. 566 (1974); *American Fruit Growers v. Brogdex Co.*, 283 U. S. 1 (1931); *Funk Brothers Seed Co. v. Kalo Inoculant*, 33 U. S. 127 (1948); and *Diamond v. Chakrabarty*, 206 USPQ 193 (1980).

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Goldman et al. (US 6,833,447).

The claim is drawn to a streptavidin-binding peptide that comprises or consists of SEQ ID No: 8, wherein position three of the peptide is either a Glu, Asp or Gly. Thus, the sequence of SEQ ID No: 8, can have additional amino acids of said sequence or be confined to being six amino acids in length (consists of).

Art Unit: 1656

Goldman et al. teach amino acid sequence 866 amino acid protein sequence from *Myxococcus xanthus*, SEQ ID No: 10786 (see Example 2) which is identical to SEQ ID No: 8 as positions 843-848 when the third position of SEQ ID No: 8 is defined as an aspartate residues (see below, Appendix A, number 1 and results in SCORE).

Qy	1	DVDAWL	6
Db	843	DVDAWL	848

Thus, inherently because the protein as taught by Goldman has the exact same sequence as that defined by SEQ ID No: 8 (when Asp is the third amino acid), said protein would be expected to bind streptavidin.

It is noted that Feit et al. (2003, J. Pat. Trade. Off. Soc., Vol. 85, No. 1, pages 5-21) teach three criteria for inherency. (1) The most important criterion is certainty. Citing *In re Tomlinson* and *In re Zierden*, Feit et al. state that certainty is established when the reference process necessarily **results** in the claimed process as opposed to a **possibility**. (2) The second criterion is chronology; it will always happen. Feit et al. state that the chronological test is forward chronology. Citing *Eli Lilly and Co. v Barr Laboratories, Inc.*, Feit et al. argue that the claimed result must always be obtained based upon the prior art method. (3) The third criterion is the legal standard. Feit et al., citing *Continental Can*, state that the legal standard is whether the missing descriptive material would be so recognized by a person of ordinary skill in the art as necessarily present in the thing.

9. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Rubenfield et al. (US 6,551,795).

Art Unit: 1656

Rubenfield et al. teach a 274 amino acid polypeptide (SEQ ID NO: 22712) from *Pseudomonas aeruginosa* which is 100% identical to SEQ ID No: 8 at positions 180-185 when glutamate is selected at position 3 (see below, Appendix A – result 2 and SCORE).

```

Qy          1 DVEAWL 6
             |||||
Db          180 DVEAWL 185

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Thus, as noted above, the polypeptide would be expected to inherently bind to streptavidin given the 100% identity between SEQ ID No: 8.

10. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Yoshida et al., (J. Bacteriol. 181:6081-6091(1999)).

Yoshida et al. teach an asparagine synthetase protein (AsnH) which is 740 amino acids in length and isolated from *Bacillus subtilis*. Said protein is 100% identical to SEQ ID No: 8 between amino acids 690 and 695 when an alanine is present at position number 3 (of SEQ ID No: 8) – see below, SCORE and p. 6085, Figure 2, AsnH (last line of the sequence alignment).

```

Qy          1 DVGAWL 6
             |||||
Db          690 DVGAWL 695

```

Thus, as noted above, the polypeptide would be expected to inherently bind to streptavidin given the 100% identity between SEQ ID No: 8.

13. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Yoshioka et al. (DNA Res. 4, 363-369, 1997).

Art Unit: 1656

Yoshioka et al. teach a conserved hypothetical protein from *Schizosaccharomyces pombe* which is 100% identical to SEQ ID No: 8 in amino acids 313-318 when aspartate is present at position 3 (of SEQ ID No: 8) –see below, or Appendix A result 4 and SCORE.

Qy	1	DVDAWL	6
Db	313	DVDAWL	318

Thus, as noted above, the polypeptide would be expected to inherently bind to streptavidin given the 100% identity between SEQ ID No: 8.

### **Conclusion**

14. It is noted that the above 35 U.S.C. 102(e and b) rejections and the references used to make such rejections are merely representative of the many different prior art rejections that could have been made under both statutes.

15. No claim is allowed.

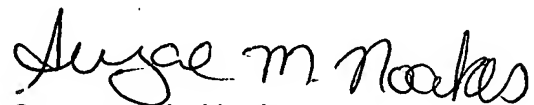
16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Noakes whose telephone number is 571-272-2924. The examiner can normally be reached on 7.00 AM-3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Art Unit: 1656

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Suzanne M. Noakes  
Patent Examiner  
Art Unit 1656